

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference ETP-10752/22	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/14104	International filing date (day/month/year) 23 JUNE 1999	Priority date (day/month/year) 23 JUNE 1998
International Patent Classification (IPC) or national classification and IPC IPC(7): C12Q 1/70; G01N 33/567; C12N 5/10 and US Cl.: 435/5, 7.21, 367		
Applicant UAB RESEARCH FOUNDATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 21 JANUARY 2000	Date of completion of this report 16 OCTOBER 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer TERRY J. DEY DONNA C. WORTMAN PARALEGAL SPECIALIST TECHNOLOGY CENTER 1601
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/14104

I. Basis of the report1. With regard to the **elements** of the international application: *

the international application as originally filed



the description:

pages 1-31

, as originally filed

pages NONE

, filed with the demand

pages NONE

, filed with the letter of



the claims:

pages 32-38

, as originally filed

pages NONE

, as amended (together with any statement) under Article 19

pages NONE

, filed with the demand

pages NONE

, filed with the letter of



the drawings:

pages 1-9

, as originally filed

pages NONE

, filed with the demand

pages NONE

, filed with the letter of



the sequence listing part of the description:

pages NONE

, as originally filed

pages NONE

, filed with the demand

pages NONE

, filed with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:



the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).



the language of publication of the international application (under Rule 48.3(b)).



the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

contained in the international application in printed form.



filed together with the international application in computer readable form.



furnished subsequently to this Authority in written form.



furnished subsequently to this Authority in computer readable form.



The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.



The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:the description, pages NONEthe claims, Nos. NONEthe drawings, sheets/fig NONE5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/14104

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims <u>1-36</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-36</u>	NO
Industrial Applicability (IA)	Claims <u>1-36</u>	YES
	Claims <u>NONE</u>	NO

2. citations and explanations (Rule 70.7)

Claims 1-36 lack an inventive step under PCT Article 33(3) as being obvious over Platt et al. in view of US Patent No. 5,026,635 to Ferguson et al. Platt et al. discloses HeLa-derived cell lines that express CXCR4 and CD4 receptors, and that are transduced to express CCR5, and demonstrates their susceptibility to infection with HIV-1 patient isolates. The cell lines of Platt et al. differ from those claimed by not using a marker gene to indicate HIV infection, and by not comprising an amplicon gene such as tat. US Patent 5,026,635 discloses HeLa-derived cell lines that comprise (1) reporter genes linked to control sequences that are activated by tat, thus being able to indicate HIV infection, and/or (2) the tat gene. It would have been obvious to one of ordinary skill in the art to construct HeLa derived cell lines comprising a reporter gene linked to a control sequence that is activated by tat and/or the tat gene as disclosed by US Patent 5,800,986 together with the CXCR4, CD4, and CCR5 HIV receptors of Platt et al. because detecting HIV infection by detecting activity of a reporter gene is a sensitive and convenient method as taught by US Patent 5,800,986.

Claims 1-36 meet the criteria set out in PCT Article 33(2) because the prior art does not anticipate cell lines that express CCR5, CXCR4, and CD4 receptors and a marker gene and methods of using such cell lines to assay for HIV infection and drug sensitivity.

Claims 1-36 meet the criteria for industrial applicability set out in PCT Article 33(4), because the claimed cell lines are useful for assaying for HIV infection and drug sensitivity.

----- NEW CITATIONS -----

US 5,026,635 A (FERGUSON et al.) 25 June 1991, see entire document.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The description is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 5 because it fails to adequately enable practice of the claimed invention because:

Practice of the invention using the specifically named cell lines J53tat and J53BL requires deposit of these cell lines under the terms of the Budapest Treaty.

Claims 10, 16, 11, 17 and 25 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because practice of the claimed invention is not enabled as required under PCT Rule 5.1(a) for the reasons set forth in the immediately preceding paragraph.

Claims 1-12, 16, 17, 21, 23, 34, 35, and 36 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason(s):

Claims 1-12 and 36 are unclear because it cannot be determined whether it is intended to claim a composition of matter for use in an assay method, or an assay method. If the claims are intended to be drawn to a method, they are incomplete because no process steps are recited.

Claims 16 and 17 lack clarity because each recites "and functional equivalents thereof"; it is not clear whether it is intended that the claims encompass both the recited cell lines and their functional equivalents, or whether the claims are intended to be drawn to the two elements in the alternative. Further, it is not clear what is meant by "functional equivalent" of a cell line, since the description defines "functional equivalent" for products such as receptors but not for cell lines.

Claim 21 lacks clarity because it is not clear how the additional step relates to determining drug sensitivity as recited in claim 20.

Claim 23 lacks clarity because it is not clear how the additional step relates to amplifying a virus as recited in claim 22.

Claims 34 and 35 lack clarity because each recites the "use of" without reciting definite properties of a product, in the case of claim 34, and without reciting definite process steps, in the case of claim 35.

Claim 36 lacks clarity because no clear additional limitations or steps are recited.

(Continued on Supplemental Sheet.)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/14104

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

VIII. CERTAIN OBSERVATIONS ON THE APPLICATION (Continued):

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/14104

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : C12Q 1/70; G01N 33/567; C12N 5/10

US CL : 435/5, 7.21, 367

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/5, 7.21, 367

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST(USPT + EPAB + JPAB + DWPI + TDBD); Dialog

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 97/28258 A (THE NATIONAL INSTITUTES OF HEALTH) 07 August 1997, see entire document.	1-36
Y	CHACKERIAN, B. et al. Human Immunodeficiency Virus Type 1 Coreceptors Participate in Postentry Stages in the Virus Replication Cycle and Function in Simian Immunodeficiency Virus Infection. Journal of Virology. May 1997, Vol. 71, pages 3932-3939, see entire document.	1-36
Y	PLATT, E.J. et al. Effects of CCR5 and CD4 Cell Surface Concentrations on Infections by Macrophagetropic Isolates of Human Immunodeficiency Virus Type 1. Journal of Virology. April 1998, Vol. 72, No. 4, pages 2855-2864, see entire document.	1-36

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
B earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

13 SEPTEMBER 1999

Date of mailing of the international search report

21 OCT 1999

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

DONNA C. WORTMAN, PH.D.

Telephone No. (703) 308-0196